

JUL 13 2005

**T-PLATE Anterior Fixation System  
Summary of Safety and Effectiveness  
April 2005**

**I. Company:** ESM Technologies  
403 Farwell Drive  
Madison, WI  
53704

**Contact:** Cliff Tribus, MD  
President, ESM Technologies  
Telephone: 608 241-5881

**II. Proposed Proprietary Trade Name:** T-PLATE Anterior Fixation System

**Classification Name:** Spinal Intervertebral Body Fixation Orthosis (per 21 CFR  
Section 888.3060  
**Product Codes:** KWQ

**III. Product Description**

The T-PLATE Anterior Fixation System is a temporary implant used for the correction and stabilization of the spine. The system is also intended to help provide temporary stabilization and to help augment the development of a solid spinal fusion. The T-PLATE Anterior Fixation System is a supplemental fixation device consisting of a variety of sizes of plates, and screws, as well as ancillary products and instrument sets. The T-PLATE Anterior Fixation System components can be locked into a variety of configurations, with each construct being tailor-made for the individual case. The implant components are made from medical grade titanium alloy. Stainless steel and titanium components must not be used together in a construct.

**IV. Indications**

The T-PLATE ANTERIOR PLATE FIXATION SYSTEM is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures. When properly used this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5) Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or

lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomeningocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

**V. Substantial Equivalence**

Mechanical testing was performed on the Anterior T-Plate fixation system, which determined it to be substantially equivalent to the PYRAMID™ ANTERIOR PLATE FLXATION SYSTEM.(K013665, SE 01/29/02).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Cliff T. Tribus  
President  
ESM Technologies, LLC  
403 Farewell Drive  
Madison, Wisconsin 53704

JUL 13 2005

Re: K051764

Trade/Device Name: T-Plate Anterior Fixation System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: KWQ  
Dated: June 29, 2005  
Received: June 30, 2005

Dear Dr. Tribus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

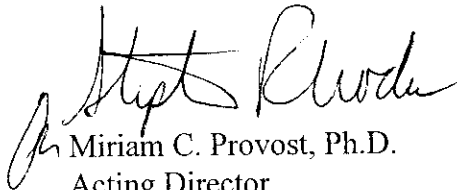
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam C. Provost", is written over the typed name.

Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative,  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known):

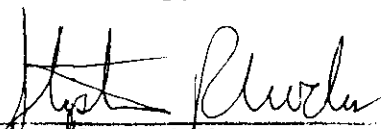
Device Name: T-PLATE Anterior Fixation SystemIndications For Use

The T-PLATE ANTERIOR PLATE FIXATION SYSTEM is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures. When properly used this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: 1) Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); 2) Pseudoarthrosis; 3) Spondylolysis; 4) Spondylolisthesis; 5) Fracture; 6) Neoplastic disease; 7) Unsuccessful previous fusion surgery; 8) Lordotic deformities of the spine; 9) Idiopathic thoracolumbar or lumbar scoliosis; 10) Deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomeningocele; and/or 11) Neuromuscular deformity (i.e., scoliosis, lordosis, and / or kyphosis) associated with pelvic obliquity.

Prescription Use X  
(Part 21 CFR 801 Subpart D)AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)

**Division of General, Restorative  
and Neurological Devices**
510(k) Number K051764